

## **MEDICAL LABORATORY BOARD MINUTES**

**Date:** April 16, 2009

**Time:** 9:00 am CDT

**Location:** Bureau of Health Licensure and Regulation  
TN Department of Health  
Heritage Place Iris Room  
227 French Landing, Ground Floor  
Nashville, TN 37243

**Members Present:** Norman Crowe, Chairman, Independent Lab Manager  
Edward McDonald, MD Pathologist, Vice-Chairman  
Steven R. Dickerson, M.D., Non Pathologist Physician  
Gloria Jenkins, Citizen Representative  
Trudy Papuchis, MD Pathologist Hospital Administrator  
Alison McDonald-Spakes, Cytotechnologist  
Christopher H. Seay, Medical Technologist  
Annie Washington, Medical Technologist  
Darius Y. Wilson, MAT, Ed.D. Educator  
Delores Voigt, MT Hospital Administrator

**Members Absent:** Jere Ferguson, MD, Pathologist (Term Expired)  
John C. Neff, MD Pathologist, Educator (Resignation)  
Yvonne Davis, Medical Technologist (Term Expired)

**Staff Present:** Lynda S. England, M.T., Director  
Ernest Sykes, Jr., Advisory Attorney  
Elizabeth Miller, Director-Health Related Boards

**Staff Absent:** Julia Daniels, Medical Technologist Consultant/ Surveyor  
East Tennessee Regional Office  
Karon Hathcoat, Medical Technologist Consultant/ Surveyor,  
West Tennessee Regional Office  
Onezean Otey, Jr., Medical Technologist Consultant/Surveyor,  
Middle Tennessee Regional Office  
Mary Hamblen, Medical Technologist Consultant/Surveyor  
West Tennessee Regional Office

**CLIA Representative:**

Ms. Bogard and surveyors were attending the state-sponsored CLIA consortium in Memphis, TN held this week.

**Minutes  
Medical Laboratory Board  
April 16, 2009**

**Quorum:** A sufficient number of board members were present to constitute a quorum.

**Called to Order:** The meeting was called to order at 9:06 am CDT by Mr. Crowe.

**New Board Member:** There were no new board appointees this quarter.

**Presiding Officer:** The meeting was conducted by Mr. Crowe; board members introduced themselves to the audience.

**Conflict of Interest Policy:**

Board members were reminded by Mr. Sykes to consider recusing themselves from any discussion or vote pertaining to meeting business if the subject material would have any relativity to board member business or any decision that would appear to be a conflict of interest.

**Board Minutes:** A motion to approve the January 14, 2009 Personnel & Education Committee minutes was made by Dr. McDonald.  
Second: Mr. Seay.

The minutes from the January 15, 2009 Board meeting were approved on a motion made by Dr. McDonald.  
Second: Ms. Voigt.

Both sets of minutes were approved by the Board.

**Board Report**

**Personnel & Education Committee:**

Ms. Wilson presented a report of the actions of the Board's Personnel & Education Committee meeting, held April 14, 2009.

Motion: Mr. Seay.  
Second: Dr. Papuchis.  
The report was approved as given.

**Minutes  
Medical Laboratory Board  
April 16, 2009**

**Contested Cases:**

No contested cases were presented during this meeting.

**Consent Orders:**

No consent orders were presented during this meeting.

**Board Report-Tennessee Professional Peer Assistance Program (TNPAP):**

Mike Harkreader, MA, RN  
TNPAP State Director

Mr. Harkreader gave the statistical report for the period July 1, 2008 to March 12, 2009 stating this advocacy agency was currently monitoring seven (7) individuals.

During this period, two (2) individuals signed monitoring agreements.

Six (6) individuals were referred to the program. The referral history included four (4) individuals having a history of arrest or drug related arrest/DUI. One (1) individual was referred to the program from the workplace via a positive urine drug screen and one (1) individual was referred to the program for working while seemingly impaired.

Six (6) were discharged from the program with two (2) individuals TNPAP considered monitoring was not necessary.

One individual refused TNPAP services, and was referred to the Department of Health.

Two individuals were noncompliant with TNPAP Monitoring services and were reported to the Department of Health.

One (1) individual successfully completed the program.

**Minutes**  
**Medical Laboratory Board**  
**April 16, 2009**

The referral sources indicated four (4) individuals  
Were referred to TNPAP relating to seeking board  
credentials while two (2) individuals were referred  
by their employer.

Motion to accept this report: Ms. Wilson.  
Second: Ms. Washington.  
Report Approved.

A copy of the TNPAP report is on file in the  
administrative office.

The full board voted to ratify the decision to renew the  
TNPAP contract made during the Personnel & Education  
Committee on April 15, 2009 with no changes in services,  
or contract fee. The contract is from July 1, 2009 to  
June 30, 2010.

Motion: Ms. Voigt.  
Second: Mr. Seay.  
TNPAP Contract Approved.

Note: Review of TNPAP materials via internet counts  
as clock hours toward continuing education credits.

A certificate of completion documenting review  
of these materials can be completed at the end of the  
internet session. Internet site: [www.TNPAP.org](http://www.TNPAP.org)

**Board Report-Rules:**  
Ernest Sykes, Jr., Board Attorney

No Rule-making hearing was conducted during this meeting.

**Minutes  
Medical Laboratory Board  
April 16, 2009**

**Ratifications:**

The following items were presented to board members for ratification per staff, state surveyor or facility request:

- 1) Exemptions for point of care testing procedures (POCT) in a licensed facility (See Attachment 1).
- 2) Initial licenses for Clinical Laboratory Facilities (See Attachment 2).

**Board Director's Report/Discussion:**

Lynda S. England BS MT (ASCP)  
Director

Ms. England gave the report which included administrative office activities performed during the past quarter.

Motion: Dr. McDonald.

Second: Mr. Seay.

Report: Approved.

The director's report is on file in the administrative office.

**Direct More Than Three (3) Labs  
Rule 1200-6-3-.13(5) Medical Lab Facilities:**

No requests were presented to the Board during the meeting.

**Reinstatement of License:**

No requests for the reinstatement of a facility license was presented for review during the meeting.

**Minutes**  
**Medical Laboratory Board**  
**April 16, 2009**

**Reports/Discussion:**

**Reports:\***

Proficiency Testing (PT) & Complaint Investigations  
Licensed Laboratory Facilities:

**East TN Regional Office: Lynda England, Director**

*Unsatisfactory/ Unsuccessful Proficiency Testing:*

The East Tennessee Regional Office reported zero (0) unsuccessful proficiency testing labs for the first quarter of 2009.

*Complaint Investigations:*

The East Tennessee Regional Office conducted zero (0) investigation(s) during the last quarter.

**Middle TN Regional Office: Lynda England, Director**

*Unsatisfactory/Unsuccessful Proficiency Testing:*

The number of licensed laboratories demonstrating a first occurrence of unsuccessful proficiency testing events (two of three events) was zero (0).

*Complaint Investigation:*

The Middle Tennessee Regional Office conducted zero (0) complaint investigation(s) during this quarter.

**West Tennessee Regional Office: Lynda England, Director**

*Unsatisfactory /Unsuccessful Proficiency Testing:*

There were zero (0) labs in this region that had an unsatisfactory or unsuccessful proficiency testing event during this quarter.

**Minutes**  
**Medical Laboratory Board**  
**April 16, 2009**

*Complaint Investigations:*

There was zero (0) complaint investigations conducted during the past quarter.

Motion: Ms. Voigt

Second: Ms. Washington.

Surveyor's Report: Approved.

- Ms. England gave the report in the surveyors' absence.

**Topics for Discussion:**

1-Elizabeth E. Culler, MD  
Medical Laboratory Director  
Blood Assurance

Dr. Culler appeared before the board to request an exemption to Rule 1200-6-3-.14(4) requiring the medical laboratory director to make periodic on-site visits at a minimum of once per month to each laboratory facility licensed in this state.

This exemption was requested because the Blood Assurance Satellite Donor Centers perform their hemoglobin analyses on the HemoCue Donor Hb Checker instruments. The daily quality control for this instrument is reviewed by both the team leader and manager at each location with quarterly audits performed and reviewed by the Medical Director.

Attorney response cited Rules 1200-6-3-.15(2) which allowed the board leeway to approve the exemption request for the donor center. **This request does not apply to the Blood Assurance main laboratory testing site.**

After discussion, board members granted this exemption request on a motion by Dr. McDonald.

Second: Dr. Papuchis.

Exemption Request Granted.

**Minutes  
Medical Laboratory Board  
April 16, 2009**

2-Revisit: Definition of FISH Testing Procedures

Staff: Attorney Sykes  
Director England

Staff and surveyors requested a revisit and discussion of the clinical laboratory test, Fluorescence In-Situ Hybridization (FISH). The purpose of this discussion was to reconcile the personnel duties and responsibilities of those individuals who triage FISH cases.

Staff requested consideration of a position statement be issued by the board which would be beneficial to surveyors who perform on-site inspections of laboratories.

Board members decided to consult a molecular pathologist for further input before adopting a position statement.

No action was taken on this subject.

**Board Report-Rules:  
Ernest Sykes, Jr.  
Advisory & Litigating Attorney**

Mr. Sykes reported on the following:

**Rules:**

*1-Continuing education, unethical conduct licensure requirements chemical terrorism exemption (06-1421) (Tenn. Comp. R. & Regs 1200-6-1-.03, .12, .18, .22; 1200-6-3-.02.)*

These rule amendments went to rulemaking hearing on December 19, 2006; they were adopted by the Board on January 26, 2007 and sent to the Attorney General for review on February 8, 2007.

The rules were signed by the Attorney General and returned to OGC in late June 2008. They will become effective by the next board meeting in July 2009.



**Medical Laboratory Board  
Minutes  
April 16, 2009**

*2-Continuing education, qualifications of testing personnel,  
use of titles in advertising (Tenn.Com. R. & Regs.  
1200-6-1-.12, .22 ,1200-6-2-08, 1200-6-3-.20)*  
These rules amendments were authorized  
on January 10, 2008 to go to rulemaking hearing.

The Justification Memo submitted March 19, 2008 received  
final approval on June 19, 2008. The rulemaking hearing  
was held on October 09, 2008, and the rules were adopted  
by the Board on that date. These rules were sent to the Attorney  
General for review and approval on April 1, 2009.

**Litigation:**

The Office of General Counsel had three (3) open cases  
pertaining to the Tennessee Medical Laboratory Board.  
A case review was scheduled for February 2, 2009.

A motion to accept this report was made by: Ms. McDonald-Spakes.  
Second: Ms. Washington,  
The report was accepted as read.

**Financial Report:  
Jim Patt  
Fiscal Office**

A copy of this report was included in the board books and is  
currently on file in the administrative office.

The report was accepted as written; no board action was taken.

**Bureau of Investigations (BIV) Report:  
Juanita Stone: Disciplinary Coordinator**

**Investigative Report 2008**

The following actions were reported to board members:  
Complaints: Twenty-three (23)  
Closed Complaints: Eleven (11)  
Closed No Action: (3)  
Closed-Referred to OGC: (8)  
Currently Opened Complaints: Thirteen (13)

**Medical Laboratory Board  
Minutes  
April 16, 2009**

All complaints must go through the Bureau of Investigations for review before they are closed or referred to the Office of General Counsel.

Motion to Accept Report: Ms. Washington  
Second: Mr. Seay  
The report was accepted as read.

**Waived Testing Procedures:**

Board members approved the addition of blood urea nitrogen (BUN) and creatinine to the waived test list for point of care testing (POCT) procedures.

Motion: Dr. Papuchis  
Second: Dr. McDonald.  
Approved.

Nay: Ms. Wilson.  
Ms. Washington.

**Review Eligibility of Medical Laboratory Director:**

No applications were submitted for board review this quarter.

**Board Policy/Position Statement:**

Position Statement: Alternate Site Testing Procedures  
Point of Care Separate License

Mr. Sykes led the discussion pertaining to the plausibility of having a separate facility license for alternate site testing procedures (point of care) granted as exemptions by the board for the performance on clinical laboratory tests outside the clinical laboratory arena. Rule 1200-6-3-.02(1) (c).

Board members discussed and approved the following Position Statement:

**Minutes  
Medical Laboratory Board  
April 16, 2009**

If a facility wishes to have a separate license, the initial application process must be completed for that separate license.

This separate license established a fire-wall between point of care testing events outside the laboratory and those clinical tests performed within the licensed laboratory so the main lab could continue laboratory testing procedures should a satellite testing location fail any required proficiency testing event.

*This separate license is not a regulatory requirement but a business decision (discretionary) by a hospital facility.*

Board members discussed and adopted this position statement with an amendment (clinical or laboratory sites) on a motion by Dr. McDonald.  
Second: Ms. Voigt.

The position statement is posted on board's web site.

**Other Business:**

**2009 Committee & Board Meeting Schedule**

<b>Committee</b>	<b>Full Board</b>
<b>July 15, 2009</b>	<b>July 16, 2009</b>
<b>October 14, 2009</b>	<b>October 15, 2009</b>

**Statement of Next Meeting:**

The next meeting will be held July 16, 2009  
beginning at 9:00 am CDT in the Iris Room,  
Heritage Place 227 MetroCenter, Nashville, TN 37243.

**Medical Laboratory Board  
Minutes  
April 16, 2009**

**Record of Adjournment:**

The meeting was adjourned at 1:45 pm CDT, on a motion properly presented by Dr. Dickerson.

Second: Mr. Seay.

Adjourn Request Approved.

**REQUEST FOR EXEMPTION-POINT OF CARE (POCT) TESTING PROCEDURES**

- 1. Baptist Riverside-Imaging Center**  
**101 E. Blount Avenue**  
**Knoxville, TN 37901-1788**

Facility Representative: Jo Ann Orr, MT (ASCP)  
Point of Care Coordinator

The board approved the following exemption request to permit the performance of BUN and creatinine by Registered Nurses, Licensed Practical Nurses and Radiology Techs utilizing the i-STAT instrument.

Motion: Dr. McDonald.  
Second: Ms. Jenkins.  
Approved.

- 2. Diagnostic Health-Knoxville**  
**601 Hall of Fame Drive**  
**Knoxville, TN 37915**

Facility Representative: Jenny Studdard  
Chief Diagnostic Officer  
Michael Calvin  
CEO Nashville Location

This request was to permit Medical X-Ray Radiologic Technicians (MXRT) and Technologists Registered with the American Registry of Radiologic Technologists (AART) to perform and report BUN\* and creatinine\* in this licensed healthcare clinic (licensed by Health Care Facilities) utilizing the SPOTCHEM®EZ instrument.

This facility is free-standing and not associated with a licensed or referral laboratory.

**Page 2**  
**Attachment 1**  
**Medical Laboratory Board/POCT Exemptions**  
**April 15, 2009**

Mr. Crowe recommended laboratory records be kept for the same time period as the imaging records (electronic/film) seven (7) years and longer if a minor.

Motion for Approval: Dr. McDonald

Second: No Second.

Motion: Withdrawn.

Board members discussed the plausibility of medical laboratory regional surveyors performing inspections on sites performing Tennessee (lab board approved) waived tests. Rule 1200-6-3-.17 (3) (h)

Any disciplinary measures would be ascribed the appropriate licensing board and not the medical laboratory board.

Dr. McDonald made a motion was made to grant conditional approval with the submission of an acceptable waived test notification form to the administrative office.

Second: Dr Papuchis.

Approved.

Nay: Ms. Wilson

Ms. Washington.

- BUN & Creatinine on Board's Waived Test List.

**NOTE: THIS INFORMATION ALSO APPLIES TO ITEM #3-DIAGNOSTIC HEALTH-NASHVILLE.**

**3.**

**Diagnostic Health-Nashville**  
**337 22<sup>nd</sup> Avenue North**  
**Nashville, TN 37203**

Facility Representative: Jenny Studdard  
Chief Diagnostic Officer

**Page 3**  
**Attachment 1**  
**Medical Lab Board/POCT Exemption Requests**  
**April 15, 2009**

This request was to permit Medical X-Ray Radiologic Technicians (MXRT) and Technologists Registered with the American Registry of Radiologic Technologists (AART) to perform and report BUN and creatinine in this licensed healthcare clinic (licensed by Health Care Facilities) utilizing the SPOTCHEM®EZ instrument.

**Board Discussion & Vote: See Item #2.**

**4. Baptist Memorial Hospital -Memphis**  
**6019 Walnut Grove Road**  
**Memphis, TN 38120**

Facility Representative: Karen Clark, BA MT (ASCP) SH  
Point of Care Manager

This request was approved to permit Registered Nurses to perform and report sodium, potassium, chloride, TCO<sub>2</sub>, creatinine, glucose, BUN, ionized calcium, hematocrit and hemoglobin in the Cardiac Cath Lab and Surgery Department utilizing the i-STAT instrument.

Motion: Dr. Dickerson.  
Second: Mr. Seay.

Note: Ms. Wilson recused herself from the discussion and vote.

**5. The Regional Medical Center at Memphis**  
**877 Jefferson Avenue**  
**Memphis, TN 37243**

Facility Representative: Brenda Oheus

After discussion, these requests were approved by board members:

1-to permit Respiratory Therapists to perform and report pH, pCO<sub>2</sub>, pO<sub>2</sub>, TCO<sub>3</sub>, oxygen saturation and base excess utilizing the IL GEM Premier 3000 blood gas analyzer in the Newborn Center

Motion: Dr. McDonald.  
Second: Ms. Jenkins.

2-the addition of Registered Nurses to a current waiver,  
performing activated clotting times (ACT's) in the Radiology  
Special Procedures Unit utilizing the AVOXimeter.

Motion: Dr. Papuchis.  
Second: Dr. McDonald.

**6. Mid-South Transplant Foundation, Inc.**  
**8001 Centerview Parkway Suite 302**  
**Memphis, TN 38018**

Facility Representative: Tory Neal, RN  
Organ Recovery Coordinator

This exemption request was to permit Registered Nurses to  
perform and report sodium, potassium, chloride, BUN, glucose,  
creatinine, ionized calcium, TCO<sub>2</sub>, hemoglobin, and hematocrit on  
brain-dead patients awaiting the donor process.  
The instrument utilized in the performance of these tests was the i-STAT.

Motion: Dr. McDonald.  
Second: Mr. Seay.

**7. Cookeville Regional Medical Center**  
**142 West Fifth Street**  
**Cookeville, TN 38501**

Facility Representative: June Cantrell  
Point of Care Manager

The representative presented the following point of care exemption  
requests for board review:

1-to permit Licensed Paramedics to perform and report activated  
clotting times (ACT's) in the Cardiac Catherization and Vascular  
Laboratory utilizing the Hemochron Elite instrument.

Motion: Dr. Papuchis.  
Second: Dr. McDonald.  
Approved.



**Minutes**  
**Medical Laboratory Board**  
**April 16, 2009**

2-to permit Licensed Paramedics to perform and report Oxyhemoglobin Saturation, Total Hemoglobin Concentration, and compute Oxygen Content measurements utilizing the AVOXimeter 1000E instrument in the Cardiac Catherization Laboratory.

Motion: Dr. McDonald.

Second: Dr. Papuchis.

Exemption Approved.

**8. Vanderbilt University Medical Center**  
**22<sup>nd</sup> & Pierce 4605 TVC**  
**Nashville, TN 37232-5310**

Facility Representative: Terri Tubb

Interim Manager Point of Care

This exemption request to was to permit Registered Nurses, and Licensed Practical Nurses to perform and report sodium, potassium, chloride, pH, pCO<sub>2</sub>, glucose, BUN, and hematocrit testing procedures in the Medical Center North Clinical Research Center utilizing the i-STAT with EC8+ test cartridge.

Motion: Dr. Papuchis.

Second: Ms. Jenkins.

Exemption Request Approved.

Note: Dr. McDonald recused himself from the discussion and vote.

**9. SkyRidge Medical Center**  
**2305 Chambilss Avenue**  
**Cleveland, TN 37312**

Facility Representative: Stacy Allison MT (ASCP)

Administrative Laboratory Director

This facility presented the following requests:

1-laboratory reduction of the Westside campus laboratory to waived status and adding the i-STAT exemption for BUN and creatinine performed in the Radiology Department at the Westside campus to the main campus license.

**Minutes**  
**Medical Laboratory Board**  
**April 16, 2009**

Laboratory license #2216 at the Westside campus was closed.

2-the addition of i-STAT exemptions to the Radiology staff/  
department to run the Chem 8 cartridge for BUN and creatinine at  
the main campus.

No action taken on this matter because of recently waived status of BUN and  
creatinine.

**INITIAL FACILITY LICENSES:**

**REGIONAL SURVEYOR RECOMMENDATION/BOARD RATIFICATION:\***

**1-Spectrum Laboratory Network**  
**625 N. Highland Avenue**  
**Murfreesboro, TN 37130**

Medical Laboratory Director: Janice J. Hessling, MD PhD  
Anatomic/Clinical Pathology  
Cytopathology

Specialties: Collection Station

Surveyor: Onezean Otey, Jr., Consultant I  
Middle TN Regional Office

Motion: Ms. Voigt  
Second: Ms. Jenkins.  
License Approved.

**2-Oral DNA Labs, Inc.**  
**214 Overlook Circle Suite 120**  
**Brentwood, TN 37027**

Medical Laboratory Director: Ronald C. McGlennen, MD  
Anatomic/Clinical Pathology  
Medical Genetics

Specialties: Molecular Diagnostics

Surveyor: Onezean Otey Jr., Consultant I/Middle TN Regional Office

Motion: Ms. Jenkins.  
Second: Ms. McDonald-Spakes.  
License Approved.

**3-Bostwick Laboratories**  
**320 Plus Park Blvd.**  
**Nashville, TN 37217**

Medical Laboratory Director: C. Michael Choi, MD  
Anatomic Pathology  
Cytopathology

Specialties: Histopathology & Non-Gyn Cytology

Surveyor: Onezean Otey Jr., Consultant I/Middle TN Regional Office

Motion: Dr. McDonald.

Second: Mr. Seay.

License Approved.

**4-Laboratory Services at Sumner Crossroads**  
**491 Sage Road Suite 100**  
**White House, TN 37188**

Medical Laboratory Director: G. Scott Hall MD  
Anatomic/Clinical Pathology  
Cytopathology

Specialties: Virology, Hematology, General Immunology, Clinical  
Chemistry, and Urinalysis

Surveyor: Onezean Otey, Jr., Consultant I/Middle TN Region

Motion: Dr. McDonald.

Second: Dr. Dickerson.

License Approved.

Note: Dr. Papuchis recused herself from the discussion and vote.

**Page 3**  
**Initial Licensure**  
**Medical Laboratory Board**  
**April 16, 2009**

**5-Plasma Biological Services**  
**3201 Gallatin Pike**  
**Nashville, TN 37216**

Medical Laboratory Director: Stacey Drott Vance MD

Specialty: Plasma Donor Center: Hct, Total Serum Protein,  
Urinalysis (Protein & Glucose)

Surveyor: Onezean Otey, Jr., Consultant I/Middle TN Region

Motion: Ms. Voigt.  
Second: Ms. Jenkins.  
License Approved.

- In the absence of the regional surveyor, Ms. England made the recommendations for initial licensure.